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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,324	01/04/2002	H. William Bosch	029318-0107	2223

7590

11/30/2005

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,324

Applicant(s)

BOSCH ET AL

Examiner

Mina Haghighatian

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 15-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Remarks filed on 11/30/04. No claims are amended, cancelled or added. Accordingly claims 1-14 remain under examination. Claims 15-34 are withdrawn.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-5, 8-14 under 35 U.S.C. 102(b) as being anticipated by Wiedmann et al (5,747,001) is maintained.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-14 under 35 U.S.C. 103(a) as being unpatentable over Weidman et al in view of Czekai et al (5,718,388) is maintained.

Response to Arguments

Applicant's arguments filed 11/30/04 have been fully considered but they are not persuasive.

Applicant argues that "Wiedmann does not teach sterile filtered nanoparticulate active agent formulations, as required by the claimed invention". Applicant continues to

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states that Wiedmann does not teach particles having an effective particle size of less than 150 nm, wherein the nanoparticulate composition is sterile filtered (see remarks, page 10). This is persuasive because Wiedmann is teaching filtration methods, such as simple filtration, e.g. sieving through a mesh filter or diafiltration using standard filtration equipment known in the art (see e.g. col. 7, lines 18-21; col. 8, lines 50-53; col. 9, lines 20-23 & 50-53). Wiedmann also teaches particle sizes of less than 400 nm, less than 250 nm and less than 100 nm (see col. 10, lines 25-39).

It is also states that "Applicants surprisingly and unexpectedly discovered that nanoparticulate beclomethasone or budesonide particles, only having tyloxapol as a surface modifier, can be prepared at a very small particle size allowing for sterile filtering". This is not persuasive either. The instant claims employ the open ended language of "comprising", which allows for other ingredients to be present in the formulation. Furthermore dependent claims 8-10 require a secondary surface modifier. Thus Applicants assertion that ONLY tyloxepol is present as the surface modifier, is not correct.

Applicant argues it is not possible to make sterile-filtered dispersions of beclomethasone or budesonide with stabilizers other than tyloxapol, thus it would not have been obvious to combine the teachings of Wiedmann and Czekai with a reasonable expectations of success. This is not persuasive because Wiedmann DOES disclose beclomethasone with tyloxapol on its surface, particle size of less than 250 or 100 nm and teaches filtration. Thus It has been shown that ALL limitations of claims

are disclosed and anticipated by Wiedmann. Czekai was employed for its teachings on particles smaller than 80 or 50 nm.

Applicant is also reminded that the instant claims are drawn to a composition, and "sterile filtration" is a method step. Composition claims are examined based on the components and not the method of making them.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
November 28, 2005



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER